CMS Guidance Document	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Executive Guidance Number 0070	Date: September 20, 2007
Planned Web Site Address http://www.cms.hhs.gov/manuals/	Release planned: October 4, 2007

PROGRAM AREA: HCPCS Codes

SUBJECT: Correction to CR 5645 – July 2007 Quarterly Update to the HCPCS Codes for Albuterol, Levalbuterol, and Reclast ${\bf @}$

APPLIES TO: Physicians, Non-Physician Practitioners, and Contractors

I. SUMMARY OF DOCUMENT: This CR corrects CR 5645 by including the Fiscal Intermediary and A/B MAC as a responsible party for Business Requirements 5735.1 and 5735.2 (previously 5645.1 and 5645.2).

II. CHANGES IN POLICY INSTRUCTIONS: (If not applicable, indicate N/A)

STATUS: R=REVISED, N=NEW, D=DELETED.

Status	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. CLEARANCES:

Clearance & Point of Contact (POC)	Name/Telephone/Component
Senior Official Clearance	Liz Richter, Director CMM, (410) 786-4164
Agency POC	Glen McGuirk, CMM/HAPG/DAS, (410) 786-5723

IV. TYPE (Check appropriate boxes for type of guidance)

	Audit Guide
X	Change Request
	HPMS
	Joint Signature Memorandum/Technical Director Letter
	Manual Transmittal/Non-Change Request
	State Medicaid Director Letters
	Other

V. STATUTORY OR REGULATORY AUTHORITY: N/A

Attachment - Business Requirements

Pub. 100-04 Transmittal: Date: Change Request: 5735

SUBJECT: Correction to CR 5645 -- July 2007 Quarterly Update to the HCPCS Codes for Albuterol, Levalbuterol, and Reclast®

EFFECTIVE DATE: July 1, 2007

IMPLEMENTATION DATE: 30 days from issuance

I. GENERAL INFORMATION

A. Background: This CR corrects CR 5645 by including the Fiscal Intermediary and A/B MAC as a responsible party for Business Requirements 5735.1 and 5735.2 (previously 5645.1 and 5645.2). Effective for claims with dates of service on or after July 1, 2007, the following Health Care Procedure Code System (HCPCS) codes will no longer be payable for Medicare:

HCPCS

Code	Short Description	Long Description
J7611	Albuterol non-comp con	Albuterol, inhalation solution, FDA-approved final product,
		noncompounded, administered through DME, concentrated form, 1
		mg
J7612	Levalbuterol non-comp con	Levalbuterol, inhalation solution, FDA-approved final product,
		noncompounded, administered through DME, concentrated form,
		0.5 mg
J7613	Albuterol non-comp unit	Albuterol, inhalation solution, FDA-approved final product,
		noncompounded, administered through DME, unit dose, 1 mg
J7614	Levalbuterol non-comp uni	tLevalbuterol, inhalation solution, FDA-approved final product,
		noncompounded, administered through DME, unit dose, 0.5 mg

In their place, the following HCPCS codes will be payable, for claims with dates of service on or after July 1:

HCPCS

Code	Short Description	<u>Long Description</u>
Q4093	Albuterol inh non-comp co	n Albuterol, all formulations including separated isomers,
		inhalation solution, FDA-approved final product, non-
		compounded, administered through DME, concentrated form, per 1
		mg (Albuterol) or per 0.5 mg (Levalbuterol)
Q4094	Albuterol inh non-comp u	d Albuterol, all formulations including separated isomers, inhalation
		solution, FDA-approved final product, non-compounded,
		administered through DME, unit dose, per 1 mg (Albuterol) or per
		0.5 mg (Levalbuterol)

In addition, a new code, Q4095 will be effective July 1, 2007, for Reclast®:

HCPCS

Code	Short Description	Long Description
Q4095	Reclast injection	Injection, zoledronic acid (Reclast), 1 mg

Currently, Reclast® 5 mg/100 ml bottle (NDC 0078-0435-61) is the only product that should be billed using code Q4095. If other products under the FDA's approval for Reclast® become available, code Q4095 would be used to bill for such products. HCPCS code J3487 (short description: Zoledronic acid; long description: Injection, zoledronic acid, 1 mg) is used to bill for products under the FDA's approval for Zometa® or such therapeutically equivalent products that may become available as identified in the FDA's Orange Book.

In summary, the following HCPCS codes are effective July 1, 2007: Q4093, Q4094, and Q4095. The following HCPCS code will no longer be payable by Medicare, effective July 1, 2007: J7611, J7612, J7613, and J7614. Code J3487 continues in use for Zometa®.

B. Policy: This instruction describes the process for updating specific HCPCS codes.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		ap	plic	abl	e co	lun	<u>nn)</u>						
		A	D	F	C	D	R	Е		Sha	red-		OTHER
		/	M	I	A	M		D		Sys	tem		
1:		В	Е		R	Е	Н	C	N	Maintainers			
					R	R	I		F	M	V	C	
		M	M		I	C			I	C	M	W	
		A	A		Е				S	S	S	F	
		C	С		R				S				
5735.1	Contractors shall no longer pay J7611, J7612,	X		X									
	J7613, and J7614, effective with dates of service												
	on or after July 1, 2007.												
5735.2	Contractors shall pay Q4093 and Q4094,	X		X									
	effective for dates of service on or after July 1,												
	2007.												
5735.3	Contractors need not search their files to either	X		X									
	retract payment for claims already paid or to												
	retroactively pay claims. However, contractors												
	shall adjust claims brought to their attention.												

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each											
		ap	plic	abl	e co	lun	ın)						
		Α	D	F	C	D	R	Е		Shar	red-		OTHER
		/	M	I	Α			D		Sys			
		В	Е		R	E	Н	C	M	laint	aineı	:S	
			3.5		R	R	Ι		F	M		C	
		M	M		I	С			I	C	M	W	
		A C	A		E R				S	S	S	F	
5525.4	A 11 1 2 21 1 1 1 1 1 1 1 1 1 1 1 1 1 1		C	3.7	K				S				
5735.4	A provider education article related to this	X		X									
	instruction will be available at												
	http://www.cms.hhs.gov/MLNMattersArticles/												
	shortly after the CR is released. You will receive												
	notification of the article release via the												
	established "MLN Matters" listserv.												

Number	Requirement	Responsibility (place an "X" in each											
		applicable column)											
		A	D	F	C	D	R	Е		Sha	red-		OTHER
		/	M	I	A			D		Sys			
		В	Е		R	Е	Н	C		Iaint			
		M	M		R I	R C	1		F	M	V	C	
		A	A		E	C			S	C	M S	W F	
		C	C		R				S	S	S	1.	
	Contractors shall post this article, or a direct link												
	to this article, on their Web site and include												
	information about it in a listsery message within												
	one week of the availability of the provider												
	education article. In addition, the provider												
	education article shall be included in your next												
	regularly scheduled bulletin. Contractors are free												
	to supplement MLN Matters articles with												
	localized information that would benefit their												
	provider community in billing and administering												
	the Medicare program correctly.												

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below: *Use "Should" to denote a recommendation.*

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk, (410) 786-5723, Glenn.McGuirk@cms.hhs.gov

Post-Implementation Contact(s): Glenn McGuirk, (410) 786-5723, Glenn.McGuirk@cms.hhs.gov

VI. FUNDING

A. For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC):

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. For Medicare Administrative Contractors (MACs):

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.